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Re-evaluation Note REV2013-14

Re-evaluation Project Plan for Fosetyl Aluminum

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Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6604-E2
Ottawa, Ontario K1A 0K9

Internet: pmra.publications@hc-sc.gc.ca
healthcanada.gc.ca/pmra
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra.infoserv@hc-sc.gc.ca

Canada

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In Canada, fosetyl aluminum is under re-evaluation by Health Canada's Pest Management Regulatory Agency (PMRA). The PMRA's pesticide re-evaluation program considers potential risks as well as the value of pesticide products to ensure they continue to meet standards of modern science and current policy established to protect human health and the environment. Under the authority of Section 16 of the *Pest Control Products Act*, the registrants of fosetyl aluminum were notified of the initiation of the re-evaluation of fosetyl aluminum. Following this, the registrant of fosetyl aluminum technical grade active ingredient in Canada indicated their intention to support all uses included on the labels of commercial class products in Canada. This Re-evaluation Note outlines a project plan and timeline for review, as well as summarizes the anticipated areas of focus related to the re-evaluation of fosetyl aluminum.

Fosetyl aluminum is an organophosphate fungicide that has been registered in Canada since 1996. Fosetyl aluminum is currently registered for control of plant diseases in food/feed crops, ornamentals and turf (Use-Site Categories 5, 6, 13, 14, 27 and 30). Registered fosetyl aluminum end-use products are formulated as wettable powders or wettable granules, for foliar or drench application.

The project plan discussed below outlines the anticipated areas of focus and risk assessments required to complete the re-evaluation of fosetyl aluminum, as well as additional data required. Should additional information become available during the re-evaluation period that affects the regulatory status of fosetyl aluminum, the PMRA will reconsider the areas of focus and risk assessments required. Currently, a proposed re-evaluation decision for fosetyl aluminum is anticipated to be published in 2015.

Re-evaluation Project Plan

Human Health Risk Assessment

The toxicology database for fosetyl-aluminum was considered complete at the time of initial registration and no major updates have been made since then. Data generated since the time of the original submission [short-term dermal toxicity study, pre-natal developmental toxicity study (non-rodent)] that may impact the hazard assessment, will be evaluated. Verification of the points of departure used for occupational and dietary risk assessment will be undertaken and areas not addressed in the original evaluation (for example, application of the *Pest Control Products Act* factor) will be reviewed. Recent scientific literature and incident reports will also be incorporated into the re-evaluation.

The dietary exposure and risk assessment previously conducted to support the registered uses will be re-evaluated to ensure they continue to meet current science standards and approaches. The dietary exposure assessment will be updated to reflect revisions to toxicological reference doses if applicable, using current food consumption data, available fosetyl aluminum usage information, as well as drinking water estimated environmental concentrations.

The occupational exposure and risk assessment will be revised to reflect the currently available scientific data and approaches, as well as revised toxicological points of departure, if applicable. A residential assessment for commercial application in residential areas will be conducted, including an aggregate assessment of exposures from the diet (food and drinking water) and residential exposures. In the absence of chemical-specific data, standard defaults will be used in the occupational and residential exposure and risk assessment.

Environmental Risk Assessment

Environmental risk assessments will be updated, where appropriate, using current methodologies, available scientific data and relevant scientific literature.

Environmental risk mitigation measures will be reviewed to ensure consistency with current label requirements.

Buffer zones for the protection of sensitive terrestrial and aquatic habitats will be calculated based on current practices and taking into consideration currently registered uses.

The Toxic Substances Management Policy (TSMP) will be taken into consideration.

Environmental fate will be reviewed to determine drinking water and expected environmental concentrations (EECs) for risk assessment purposes.

Value

The value of fosetyl aluminum will be considered. The viability of alternatives will be examined if risks of concern are identified.

Data Requirements

Additional data requirements related to toxicology, dietary exposure and environment assessments have been identified for fosetyl aluminum and were requested from the technical registrant (Appendix I).

Anticipated Timeline for Re-evaluation

A proposed re-evaluation decision for fosetyl aluminum is anticipated to be published for consultation in 2015.

Additional Information

PMRA documents can be found in the Pesticides and Pest Management section of Health Canada's website at healthcanada.gc.ca/pmra. PMRA documents are also available through the Pest Management Information Service. Phone: 1 800 267-6315 within Canada or 1 613-736-3799 outside Canada (long distance charges apply); fax: 613-736-3798; e-mail: pmra.infoserv@hc-sc.gc.ca.

Appendix I Data Requirements for the Re-evaluation of Fosetyl aluminum

Toxicology

DACO 4.3.5 Short-term dermal 21/28 day
DACO 4.5.3 Prenatal Developmental Toxicity (non-rodent)

Dietary Exposure

DACO 6.3 Metabolism is plants
DACO 7.3 Freezer Storage Stability
DACO 7.4.1 Supervised Residue Trial Study

Environment

DACO 9.3.3 Daphnia sp. Chronic (Life-Cycle)